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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,125	09/17/2001	Christophe Marcireau	A3233A US	2418

5487 7590 03/18/2003

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,125

Applicant(s)

MARCIREAU ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,17-19,24 and 27-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-16, 20-23,25,26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This application is a 371 of PCT/EP99/05142 published in English as WO 00/05362 on February 3, 2000.

The preliminary amendment filed on January 16, 2002 amending the specification to insert the cross-reference to the prior applications has been entered.

Claims 1-44 are pending. Claims 28-44 are withdrawn.

Election/Restriction

Applicant's election with traverse of Group I(a), drawn to sequence encoding SEQ ID NO:2, in Paper No. 13 filed January 10, 2003 is acknowledged. The traversal is on the ground(s) that "Page 2, lines 22-35 through page 3, lines 1-4 of the instant Specification make clear that SEQ ID NOs: 2 and 8 are polypeptide sequences for a MEKK interacting FHA protein(MIF1). Thus, SEQ ID NOs: 2 and 8 share "a special technical feature". Moreover, it is Applicants' position that these polypeptide sequences are new, useful and unobvious over the prior art" (Remarks, page 3). This is not found persuasive because SEQ ID NOs: 2 and 8 and DNAs encoding thereof represent different products such as structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. 37 CFR

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1.475 does not provide for multiple products or methods within a single application and therefore unity of invention is lacking with regard to Groups I(a) and I(b).

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 5, 17-19, 24 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group I(b), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Claims 1-3, 6-16, 20-23, 25 and 26 are under consideration.

Claim Objections

Claims 1, 6-16, 20-22, 25 and 26 are objected to under 37 CFR 1.75(d)(1) as being in improper form because the claim states an improper Markush group. Compounds included within a Markush group must (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility (See MPEP 803.02.) While SEQ ID NO:2 and SEQ ID NO:8 recited in claims 1, 6-16, 20-22, 25 and 26 may share the common utility of being MIF1, the specification does NOT disclose that the compounds share a substantial structural feature disclosed as being essential to that utility. Because a substantial structural feature is not disclosed as being essential to the utility that is common to the claimed species, the claim states an improper Markush group.

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Claims 1, 20 and 26 are objected to because of the following: MEKK and FHA should be spelled out and followed by the abbreviations in parenthesis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, with dependent claims 6-16, 20-22, 25 and 26, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (a) is drawn to a DNA encoding MIF1 that can be amplified using specific primers. Claim 1 (b) is drawn to a DNA that hybridizes under undefined stringent conditions to SEQ ID NO:1. Claim 1 (c) is drawn to a DNA encoding splice and allelic variants of SEQ ID NO: 1. Claim 1 (d) is drawn to a DNA encoding a polypeptide which specifically binds to an antibody against residues 16-28 of SEQ ID NO:8.

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Because hybridization conditions are not defined and there is no limitations on the structure of a gene amplified using the specific primers, the structures of MIF1 and DNA encoding thereof encompassed by the claimed genera include species which are widely variant in structure and function (see 112, 2nd paragraph, rejection).

Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus, SEQ ID NO:1. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties and fails to provide any structure: function correlation present in all members of the claimed genus.

There is no description in the specification of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO:1 relates to the structure of any naturally occurring alleles. The general knowledge in the art concerning alleles does not provide any indication of how one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art structure of one does not provide guidance to the structure of others. Similarly, there is no description of any splice variant other than SEQ ID NO:1.

As such, the description of SEQ ID NO:2 and a DNA encoding thereof of SEQ ID NO:1 is insufficient to be representative of the attributes and features of the entire

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genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, with dependent claims 6-16, 20-23, 25 and 26, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the term "MEKK interacting FHA protein (MIF1)" does not clearly define the protein function. The interaction between two proteins can be indirect and direct. If it is direct such as binding, for example, it should be defined which effect said binding produces such as inhibitory, stimulatory, etc. Therefore, without defining the interaction there is no way of knowing what are the metes and bounds of the claim. Furthermore, "MEKKs represent an expanding family of kinases" with different properties (e.g., specification page 1, lines 22-30). The metes and bounds of the claims are indefinite without knowing the MEKK with which the claimed protein is interacting.

Furthermore, the claim 1(b) recites "stringent conditions". Said conditions can mean different conditions in different experiments. As result, DNAs of different structures will hybridize under different conditions rendering the scope of the claims

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unascertainable. Claim 1(d) recites "specifically binds to an antibody". Many different polypeptides may be construed as specifically binding to an antibody. Without definition of this term, there is no way of knowing which polypeptides are encompassed by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 6-16, 20-23, 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Ren et al.

Ren et al. (May 1, 1998, form PTO-1449, reference B) teach the protein of 462 amino acids that comprises SEQ ID NO:2 of the instant invention (page 735, Figure 1). They teach a DNA encoding thereof comprising SEQ ID NO:1 of the instant invention (GenBank accession AF015308, specification at page 2, lines 13-15). They teach a mouse ortolog thereof (GenBank accession AF015309, page 734, footnote, and page 735, Figure 1). Ren et al. teach vectors and host cells comprising said DNA and its expression. The DNA disclosed by Ren et al. will hybridize to SEQ ID NO:1, is its

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naturally-occurring variant and encodes a polypeptide that will specifically bind to an antibody to which SEQ ID NO:2 binds.

Ren et al. name the protein "58- kDa microspherule protein (MSP58)" and demonstrate its interaction with nucleolar protein p120. However, whether or not the interaction disclosed by Ren et al. ultimately represents the same function as is discussed in the instant application, the protein remains the same. As such, the protein MSP58 and DNA encoding thereof disclosed by Ren et al. anticipate claims 1-3, 6-16, 20-23, 25 and 26.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

March 14, 2003